

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/36

Issued: 14 July 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	✓



HEALTH ESTATES

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Abbott AxSYM laboratory analyser Abbott AxSYM <i>Plus</i> laboratory analyser	▶ ①
Problem: Reports of false results.	▶ ②
Action by: Directors of Pathology Laboratory Quality Managers	▶ ③
Action: <ul style="list-style-type: none"> Report instances of unexpected false results to the NIAIC and to the manufacturer Ensure that you have systems in place for the routine reporting of unexpected false results to the NIAIC and to the manufacturer 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC NIAIC is seeking further information on the occurrence of unexpected false results in order to establish whether there is a wider problem with this analyser and whether there is a need for further advice.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Abbott AxSYM laboratory analyser

Abbott AxSYM *Plus* laboratory analyser

2. PROBLEM:

The Abbott AxSYM and AxSYM *Plus* laboratory analysers are used in pathology laboratories to process a wide range of diagnostic tests.

NIAIC have been made aware by MHRA of reports of false results from laboratories using the AxSYM and AxSYM *Plus* laboratory analysers, as follows:

- three unrepeatable false negative results from one centre using an HIV assay on the AxSYM *Plus*
- four unrepeatable false negative results from one centre using a rubella IgG assay on the AxSYM

Initial investigations suggest three potential causes of these false results:

1. A blocked process probe. Abbott advises that a blocked process probe could lead to:
 - control results that are out of range
 - visual evidence of splashing on or around the process probe
 - damage to the probe
 - system error codes
 - false results.
2. Unrecovered probe crashes.
3. Wrong sample tubes. The dimensional specifications of sample tubes to be used in combination with the AxSYM are given in the AxSYM operation manual (section 5-35). Abbott advises that sample tubes outside this specification could lead to false results.

3. ACTION BY:

Directors of Pathology

Laboratory Quality Managers

4. ACTION:

- Report instances of unexpected false results to the NIAIC and to the manufacturer
- Ensure that you have systems in place for the routine reporting of unexpected false results to the NIAIC and to the manufacturer

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Clinical Chemistry Departments
- Directors of Pathology
- Haematology Departments
- Immunology Departments
- Laboratory quality managers
- Medical Microbiologists
- Microbiology Departments
- Directors of Laboratory Services

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Caryn Broeksma
Quality and Regulatory Manager
Abbott Diagnostics
Abbott House
Norden Road
Maidenhead
Berkshire
SL6 4XF

Tel: 01628 644 235

Fax: 01628 644 440

E-mail: caryn.broeksma@abbott.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/36 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

NIAIC is seeking further information on the occurrence of unexpected false results in order to establish whether there is a wider problem with this analyser and whether there is a need for further advice.



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety